IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO WAVE 8 CASES ON ATTACHED EXHIBIT "A"	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF PETER SAND, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson ("Ethicon") hereby respond in opposition to Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Peter Sand, M.D. [ECF No. 6886] ("Motion") and Memorandum of Law in Support of Plaintiff's Motion to Exclude Opinions and Testimony of Peter Sand, M.D. [ECF Nos. 6890] ("Mem."), as follows:

Ethicon has disclosed Dr. Peter Sand, MD, a board-certified urogynecologist, as a general expert. Plaintiffs' challenge Dr. Sand's opinions concerning the safety and efficacy of the TVT. For the reasons stated below, the Court should deny Plaintiffs' Motion in its entirety.

ARGUMENT

I. Dr. Sand is qualified to offer testimony concerning the clinical effects (or lack thereof) of degradation and cytotoxicity.

Plaintiffs challenge Dr. Sand's opinions concerning the "design and material properties of the TVT." However, Dr. Sand does not intend to offer opinions on the chemical processes of degradation or cytotoxicity or opinions concerning the mechanical differences between laser-cut and machine-cut mesh. Instead, Dr. Sand will offer opinions concerning the safety and efficacy of

TVT, including opinions about the clinical effects of alleged defects in mesh "design" or "biomaterials" used for mesh. This is precisely within the scope of Dr. Sand's qualifications, and his general causation opinions related to these issues were derived using reliable methodology.

In his general report, Dr. Sand does not offer any opinions about how to design mesh, the chemical processes underlying degradation or cytotoxicity, or other similar opinions beyond the scope of clinical study. Instead, Dr. Sand offers opinions concerning the lack of any clinical presentation from the alleged degradation and cytotoxicity of TVT mesh. For example, Dr. Sand's report includes the following opinion:

> TVT is made from Prolene polypropylene. Given the number of medical products that are acceptable for use within the human body that are comprised of polypropylene, ***the safety of mesh made from polypropylene is well documented and accepted within the medical community*** – as the data in my report clearly shows. As for degradation or cytotoxicity of polypropylene, I am not aware of any valid medical research or literature supporting this. I am aware of discrepant in vitro cell line testing that reported cytotoxicity, which was submitted to the FDA in the TVT 510k, but ***the other data and in particular the human clinical data showed no evidence of cytotoxicity.*** If the TVT mesh were cytotoxic, then it would not incorporate into the body. Instead there would be necrosis and the body would reject the TVT mesh in all cases. As discussed, ***the clinical data do not support this.*** Further, I have not experienced this in my clinical practice, nor have I experienced or seen any evidence of the mesh causing chronic systemic inflammation or degrading.

Mot. Ex. B, Sand General Report at 12 (emphasis added).

These are precisely the type of clinical opinions related to cytotoxicity and degradation this Court has allowed other urogynecologists to offer. *See, e.g.*, *In re Ethicon, Inc.*, MDL No. 2327, 2016 WL 4944907, at *3 (S.D. W. Va. Aug. 30, 2016) ("Dr. Zaslau—a board-certified urogynecologist who has performed hundreds of TVT implants and removals—is qualified to testify about degradation from a clinical perspective, such as mesh's reaction to and effect on the human body."); *In re Boston Sci. Corp.*, MDL No. 2326, 2018 WL 2425955, at *2 (S.D. W. Va. May 29, 2018) ("Dr. Kohli is an experienced urogynecologist, and he has performed many

surgeries implanting and removing polypropylene mesh devices used for the treatment of SUI. I have generally found that such experience qualifies physicians to opine on the properties of polypropylene irrespective of a lack of specialized knowledge of biomaterials.").

With respect to Dr. Sand, there is no reason to depart from the Court's prior holdings on this issue. Dr. Sand is a board-certified urogynecologist who has been practicing medicine since 1980. *See* Mot. Ex. B, Sands General Report at 1 [ECF No. 6886-2; PageID# 182079]; Mot. Ex. C, Sand 9/26/18 Dep. Tr. 6:14–7:11 [ECF No. 6886-3; PageID# 182101]. He has implanted approximately 500 TVT retropubic slings, as well as approximately 1,500 Boston Scientific Advantage Fit slings. *Id.* at 61:22–62:13 [ECF No. 6886-3; PageID# 182114–15]. He also has experience in a "wide variety of biomaterials in surgery," (Mot. Ex. B, Sands General Report at 4 [ECF No. 6886-2; PageID# 182082]), including polypropylene mesh for the treatment of pelvic organ prolapse. Mot. Ex. C, Sand 9/26/18 Dep. Tr. 91:14–92:20 [ECF No. 6886-3; PageID# 182122]. He has served as a principal investigator for more than 40 studies, including numerous studies on stress incontinence treatments. *See* Mot. Ex. D, Sand CV pp. 7–10 [ECF No. 6886-4; PageID# 182138–41]. He has authored or coauthored nearly 300 articles or book chapters, including numerous publications related to synthetic slings. *See id.* at pp. 10–28 [ECF No. 6886-4; PageID# 182141–59].

Further, Dr. Sand used reliable methodology in coming to his conclusions regarding cytotoxicity and degradation. In addition to his extensive experience, his opinions were based on a review of dozens of peer-reviewed articles related to synthetic midurethral slings such as the TVT. *See* Mot. Ex. B, Sand General Report pp. 15–20 [ECF No. 6886-2; PageID# 182093–98] (reference list). To the extent Plaintiffs believe there is additional literature that does suggest

clinical effects from degradation or cytotoxicity of TVT, that is an issue of weight, not admissibility.

Accordingly, Dr. Sand is qualified to offer opinions concerning the lack of clinical effects of alleged degradation and cytotoxicity, and these opinions were derived using reliable methodology. The Court should deny Plaintiff's Motion on this point.

II. Dr. Sand is qualified to offer opinions related to the safety and efficacy of TVT, and these opinions are reliable.

Plaintiffs' second attack on Dr. Sand's opinion is that he has not used the TVT retropubic specifically in several years, rendering him unqualified to offer opinions concerning the TVT and rendering his opinions on the safety and efficacy of the TVT unreliable.

This argument is meritless. This Court has repeatedly permitted Plaintiffs' experts who have never implanted a pelvic organ prolapse device or a midurethral sling to offer testimony about the safety and efficacy of these products. *See, e.g.*, *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 713 (S.D. W. Va. 2014) (finding Plaintiffs' expert, Dr. John Steege, qualified to testify about safety and efficacy of TVT-O despite never performing a mesh-related procedure to treat stress incontinence). More broadly, this Court has routinely allowed urogynecologists to offer opinions on safety and efficacy, even though the expert did not have extensive experience with the exact product at issue. *See, e.g.*, *Carlson v. Boston Sci. Corp.*, No. 2:13-cv-05475, 2015 WL 1931311, at *11 (S.D. W. Va. Apr. 28, 2015) ("Federal Rule of Evidence 702 does not necessarily require specific clinical experience implanting the device at issue."). The Court has also routinely allowed experts in this litigation to apply safety and efficacy data for other similar mesh slings to the particular product at issue. *See, e.g.*, *Flandro v. Boston Sci. Corp.*, No. 2:13-cv-17027, 2016 WL 3282734, at *13 (S.D. W. Va. June 14, 2016) ("I find there is a 'valid scientific connection' between data and studies about other mid-urethral polypropylene slings and the Advantage sling."

(citing *Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *19 (S.D. W. Va. May 6, 2015)).

Whether Plaintiffs' argument about Dr. Sand's personal experience with TVT is an attack on his qualifications or the reliability of his opinions, the Court should reject Plaintiffs' arguments. As noted above, Dr. Sand has extensive experience with synthetic midurethral slings generally, having implanted over 2000 such slings during his career. The fact that "only" 500 of these slings were TVT retropubic specifically does not render him unqualified to opine about the TVT; in fact, it's 500 more TVTs than many of the Plaintiffs' experts who have been permitted to testify over defense objection. Dr. Sand is a preeminently qualified urogynecologist who can reliably apply his broad experience with and specialized knowledge of suburethral slings to the TVT.

Further, Dr. Sand's opinions were based, in part, on a review of literature concerning polypropylene mesh slings similar to the TVT, including numerous studies specific to Ethicon's retropubic TVT. *See* Mot. Ex. B, Sand General Report pp. 15–20 [ECF No. 6886-2; PageID# 182093–98] (citing numerous studies specific to TVT retropubic, such as Nilsson and Ulmstem studies). Plaintiffs do not explain how Dr. Sand's literature review was lacking, nor do they identify particular contradictory studies that Dr. Sand failed to consider.[1] Plaintiffs also ignore that Dr. Sand's safety and efficacy opinions are further supported by his extensive training, education, knowledge, and clinical experience implanting nearly 2000 or more similar polypropylene mesh slings.

[1] Plaintiffs' reliance on *Wineberger v. Boston Sci. Corp.*, No. 2:13-cv-28892, 2015 WL 1887222 (S.D. W. Va. Apr. 25, 2015), is misplaced. In that case, the Court excluded Dr. Shull's opinions concerning product design because Dr. Shull could not demonstrate any knowledge of the objective design procedures from which the manufacturer supposedly deviated. *See id.* at *14. Nothing in *Wineberger* could be read as requiring an expert urogynecologist to spell out specific objective criteria for a literature review or prohibits an expert from forming opinions based on his training, education, and experience.

To the extent that Plaintiffs seek to exclude Dr. Sand based on the perceived inaccuracy of his reliance list, this argument also fails. Dr. Sand's report lays out specifically, with endnotes, what literature supports his opinions. *See* Mot. Ex. B, Sand General Report pp. 15–20 [ECF No. 6886-2; PageID# 182093–98] (reference list). Even assuming Dr. Sand has not yet reviewed certain internal Ethicon documents listed on his reliance list, that does not go to the reliability of his literature review. Plaintiffs have not identified a single peer-reviewed article referenced in Dr. Sand's report or his reliance list that Dr. Sand did not actually review. Further, Plaintiffs' argument ignores that Dr. Sand's opinions are based on both his literature review and his overall experience, training, education, and specialized knowledge. The mere overinclusion of certain company documents on a reliance list does nothing to undermine the reliability of Dr. Sand's opinions.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Peter Sand, M.D.

Dated: October 24, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 24, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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